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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,190	02/20/2001	Klaus-Dieter Vorlop	64251-010	9277

7590 04/23/2004

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EXAMINER	
REDDICK, MARIE L	

ART UNIT	PAPER NUMBER
1713	

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No.	Applicant(s)	
	09/720,190	VORLOP ET AL.	
	Examiner	Art Unit	
	Judy M. Reddick	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/29/03;03/23/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-30* is/are pending in the application.

4a) Of the above claim(s) *25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 & 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/03 has been entered.

Election/Restrictions

2. The Examiner, as per having been drawn to a nonelected invention, withdraws claims 25-30 from further consideration. See the previous Office Action(paper no. 10, 08/27/03, paragraph no. 1.).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 3, 7 & 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As far as the Examiner can tell, no support can be found for recited "wherein the polyvinyl alcohol solution has a concentration of 4-30 wt.%, exclusive of the additive and exclusive of the biologically active material", "wherein the polyvinyl alcohol solution has a concentration of 6-16 wt. %, exclusive of the additive and exclusive of the biologically active material", "wherein the additive has a concentration in a range of 4-20 wt.%, exclusive of the additive and exclusive of the biologically active material" and "wherein the additive has a

concentration in a range of 6-10 wt. %, exclusive of the additive and exclusive of the biologically active material" per claims 2, 3, 7 & 8, respectively, and, without any iron-clad guidelines from applicant as to where support might be found, this, as such, engenders a New Matter situation. Furthermore, Applicants are directed to page 5 @ lines 5-7 wherein it states "polyethylene glycol is a preferred water-soluble additive that is added at a concentration of 4 to 30 wt.%, preferably at 4-20 wt.%, and more preferably at 6 to 16 wt.%". Furthermore, there is nothing supporting that the concentration of "polyethylene glycol"(claims 7 & 8) is based on "polyvinyl alcohol + water".

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 3, 7, 8 and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The recited "wherein the polyvinyl alcohol solution has a concentration of 4-30 wt.%, exclusive of the additive and exclusive of the biologically active material" per claim 2 and "wherein the polyvinyl alcohol solution has a concentration of 6-16 wt. %, exclusive of the additive and exclusive of the biologically active material" per claim 3 constitutes indefinite subject matter as per it not being readily ascertainable as to whether the "solution"(polyvinyl alcohol + water) or the "polyvinyl alcohol" component is intended to have the recited concentration. Further, it is not clear as to the exact entity that the recited ranges are being based on, "polyvinyl alcohol + water", "polyvinyl alcohol + water + unrecited ingredient(s)" other than the "additive" and "biologically active material" or other.

B) The recited "wherein the additive has a concentration in a range of 4-20 wt. %, exclusive of the additive and exclusive of the biologically active material" per claim 7 and "wherein the

additive has a concentration in a range of 6-10 wt. %, exclusive of the additive and exclusive of the biologically active material " per claim 8 constitutes indefinite subject matter as per it not being readily ascertainable as to how the recited concentration of the additive can be based on components exclusive of the "additive".

C) The recited "wherein a gel substance form" per claims 13, 14 & 15 constitutes indefinite subject matter as per it not being readily ascertainable as to how said "form" further limits the antecedently recited "process for producing a bio-catalyst".

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-19 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charmot et al(U.S. 4,737,533).

Charmot et al disclose dry material which can be hydrated into an aqueous gel comprising (1) a matrix comprising a macromolecular substance A which includes proteins, capable of forming a porous aqueous gel when it is in the presence of water, (2) a water-soluble linear polymer B which includes polyethylene glycols governed by a weight average molecular weight of about 1,000 and polyvinyl alcohol, (3) a plasticizer for the macromolecular substance A which includes polyethylene glycols having a weight average molecular weight of less than 400 and, (4) dispersed in the matrix, particles of a polymer C obtained from at least one water-immiscible monomer. Charmot et al further teach that the antecedently recited material can be obtained by mixing an aqueous solution of macromolecular substance A with the polymer B, the plasticizer and a latex of polymer C, followed by cooling, shaping and drying of the aqueous gel obtained. The dry material can be used in biological applications after rehydration. Charmot et

al, @ col. 4, lines 39 – 52, teach that polymer C may be "sensitized" which means that biologically active substances such as antibodies, antigens, drugs and enzymes are immobilized on the particles of polymer C and that the particles of polymer C included in the matrix are polymer particles which can be magnetized. More specifically, Charmot et al @ col. 5, lines 2-40 teach that the dry material which can be hydrated is obtained via (1) mixing (a) an aqueous solution of a macromolecular substance A capable of forming, after preferably cooling to a temperature of 30 to 80 degree C, a porous aqueous gel when the substance A is in the presence of water, at a preferred concentration of the substance A effective for forming the gel at a temperature of 30 to 80 degrees C, (b) a water-soluble linear polymer B, (c) a plasticizer for the macromolecular substance A, and (d) a latex of a polymer C and wherein mixing occurs at a temperature greater than the gelling temperature of the aqueous solution of the macromolecular substance A; 2) cooling the resultant mixture to a temperature less than the gelling temperature of the aqueous solution of the macromolecular substance A and shaping the aqueous gel obtained during the cooling wherein, the shaping process consists of pouring the mixture obtained in the mixing stage onto a support consisting of a transparent thermoplastic plate which is placed on a horizontal glass plate, allowing the mixture to cool to form an aqueous gel which adheres to the plate, and covering the aqueous gel film with a regenerated cellulose-based sheet soaked in an aqueous solution of glycerol wherein the sheet of regenerated cellulose is folded back under the glass plate and (3) drying the shaped aqueous gel at a temperature less than the gelling temperature of the aqueous solution of the macromolecular substance A. Charmot et al @ col. 6, lines 46-66 also teach that a gel in the form of a film may be obtained by pouring the mixture on a glass plate and allowing it to cool to convert the liquid film deposited into an aqueous gel film. The aqueous gel film may then be demolded and dried. Lastly Charmot et al @ col. 7, lines 3-22 teach that the product is particularly valuable for its uses in biological applications, the porous nature of the gel of the macromolecular substance A enables proteins to reach the particles of polymer C and to become bound thereto by absorption or covalency and the dry material which can be hydrated

into an aqueous gel containing dispersed polymer particles and has the advantage of combining the positive properties of the matrix, i.e., of being (1) capable of being hydrated at the desired time into a porous aqueous gel in such forms as films, plates, sticks, pellets and beads which can be easily handled, (2) compatible even with aqueous media with high concentrations of electrolytes, and (3) permeable to high molecular weight proteins, with the positive properties of the polymer particles derived from a water-immiscible monomer, viz. having a high and controlled specific surface area and a wide range of available chemical groups on the surface. See, e.g., the Abstract, cols. 1, 2, 4-7, the Runs and claims of Charmot et al.

The disclosure of Charmot et al differs basically from the claimed invention as per the non-specificity relative to the polyvinyl alcohol component, as claimed. However, the "polyvinyl alcohol" component per Charmot et al is generic to the claimed "polyvinyl alcohol" component and necessarily implies that any "polyvinyl alcohol", including the claimed "polyvinyl alcohol" would have been operable within the scope of patentees invention and with a reasonable expectation of success. Moreover, the use of any commercially available polyvinyl alcohol component in lieu of the polyvinyl alcohol component of Charmot et al would have been obvious to the skilled artisan and with a reasonable expectation of success, criticality for such, commensurate in scope with the claims, not have been demonstrated on this record. Moreover, as to the content of water removal, although generic, such is a necessary implication that any water content removal, including the claimed content of water removal, would have been operable within the scope of patentees invention and with a reasonable expectation of success, absent a clear showing of unexpected results, commensurate in scope with the claims. While Charmot et al do not expressly recognize the generation of a "bio-catalyst" from the disclosed process, motivation in the prior art does not have to be the same as that for the claimed invention as provided for under the guise of In re Kemps, 30 USPQ2d 1309(Fed. Cir. 1996). Moreover, the formation of the here recited bio-catalyst would merely follow as a necessary incident to the selection of the recited steps based solely on the motivation or suggestion

provided in Charmot et al. It would be reasonably expected that a phase separation of the polyvinyl alcohol solution of Charmot et al, as modified, would occur since the process parameters and components of Charmot et al, as modified, are essentially the same as the claimed process parameters and components and in the absence of the USPTO to have at its disposal the tools and facilities deemed necessary to make physical determinations of this sort. As to the remaining process parameters of the dependent claims, the limitations are either taught by Charmot et al, suggested by Charmot et al or would have been obvious to the skilled artisan and with a reasonable expectation of success. More specifically, any additional or particular claim parameters which may not be specifically set out in the references are considered not to involve anything unobvious absent a showing to the contrary.

Claim Rejections - 35 USC § 103

9. Claims 1-19 & 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkatraman et al(U.S. ,039,977).

Venkatraman et al teach pharmaceutical formulations. More particularly, Venkatraman et al teach pharmaceutical hydrogel formulations containing polyvinyl alcohol, water, a therapeutically effective amount of a drug and other additives which are useful in a variety of contexts, including electrotransport drug delivery, methods for making the formulations, electrotransport drug delivery systems containing the hydrogel formulations as drug reservoirs and methods for substantially eliminating syneresis in a polyvinyl alcohol hydrogel system, said method involving selecting a degree of hydrolysis and corresponding percent by weight of polyvinyl alcohol in the gel that is effective in forming a hydrogel which is stable to syneresis. In making the formulations, Venkatraman et al teach that the method entails dissolving a predetermined amount of polyvinyl alcohol in an aqueous liquid, combining the polymer solution with a therapeutically effective amount of drug and other additives, and gelling the solution by a freeze-thaw process in which thawing is conducted for a time period of 5 hours or less. The resultant hydrogel is mechanically strong and stable to syneresis. The formulation

may be used to form a drug reservoir for passive transdermal drug delivery or for electrotransport drug delivery. Venkatraman et al further teach that alternatively, the formulation may be combined with a pharmaceutically acceptable carrier suitable for other modes of drug administration wherein, suitable carrier materials include, inter alia, polyethylene glycol(sufficient to meet the additive b) per the claimed invention). More specifically, Venkatraman et al teach that an alternative method for incorporating the drug and other desired additives into the hydrogel involves forming the gel in the absence of drug, removing the water(dehydrating), and hydrating the gel with an aqueous drug solution containing the other desired additives. Venkatraman et al teach that this method is particularly useful for drugs and/or formulation additives that are heat-sensitive. Most specifically, Venkatraman et al @ col. 9, lines 1+ teach that the invention is also useful in conjunction with the electrotransport delivery of proteins, peptides and fragments thereof(sufficient to meet the biologically active material c) per the claimed invention), whether naturally occurring, chemically synthesized or recombinantly produced. See, e.g., the Abstract, col. 1, lines 1-15. col. 3, lines 29-67, col. 4, lines 1-67, col. 5, lines 6-65 and cols. 6-9 of Venkatraman et al. In terms of the polyvinyl alcohol component of the hydrogel, Venkatraman et al @ least at col. 5, lines 56+ teach that the percent by weight of polyvinyl alcohol in the hydrogel, Y, is selected to correspond to the degree of hydrolysis of the polymer, Dh. When the Dh is in the range of approximately 95% to 99.9%, Y is in the range of approximately 10 wt. % to 30 wt. % and preferably, in the range of approximately 96% to 99% and Y is in the range of approximately 12 wt. % to 25 wt. %, sufficient to meet the limitations per the instantly claimed invention.

The disclosure of Venkatraman et al differs basically from the claimed invention, with the understanding that the claimed steps are not required to be performed in a sequential fashion, in that the content of water removal, although not expressly disclosed, is generic to the claimed water removal content and therefore necessarily implies that any amount of water removal, including the claimed content of water removal, would have been operable within the scope of patentee's invention and with a reasonable expectation of success, absent a clear showing of

criticality for such clearly commensurate in scope with the claimed invention. As to the remaining process parameters per the dependent claims, the disclosure of Venkatraman et al is generic to these parameters which necessarily implies that any process parameters, including the claimed process parameters, would have been operable within the scope of patentee's invention and with a reasonable expectation of success. Venkatraman et al is provided by virtue of 102(e).

While Venkatraman et al do not expressly recognize the generation of a "bio-catalyst" from the disclosed process, motivation in the prior art does not have to be the same as that for the claimed invention as provided for under the guise of In re Kemps, 30 USPQ2d 1309(Fed. Cir. 1996). Moreover, the formation of the here recited bio-catalyst would merely follow as a necessary incident to the selection of the recited steps based solely on the motivation or suggestion provided in Venkatraman et al . It would be reasonably expected that a phase separation of the polyvinyl alcohol solution of Venkatraman et al , as modified, would occur since the process parameters and components of Venkatraman et al , as modified, are essentially the same as the claimed process parameters and components and in the absence of the USPTO to have at its disposal the tools and facilities deemed necessary to make physical determinations of this sort.

Response to Arguments

10. Applicant's arguments filed 12/29/03 have been fully considered but they are not persuasive.

Relative to the 112, 2nd paragraph issues----While Counsel, in a good faith effort, attempted to remedy the 112, 2nd paragraph issues raised in the previous Office Action, some remain and new 112, 1st and 2nd paragraph issues have been created, as set forth supra.

Relative to Charmot et al---It is urged and maintained that the instantly claimed invention is obvious within the meaning of 35 USC 103(a) over Charmot et al as per reasons clearly stated in the Grounds of Rejection supra.The crux of Counsel's arguments appear to hinge on there being no teaching, suggestion or motivation per Charmot et al to the gelling of the polyvinyl alcohol,

this being because Charmot et al do not teach, suggest or motivate the dehydration step d as recited per the inventive claims. With all due respect to the opinion of Counsel, Charmot et al clearly, at lines 30-31, teach that an aqueous gel is derived from a mixture containing (b) a water-soluble linear polymer such as polyvinyl alcohol. As to the content of water removal, although generic, such is a necessary implication that any water content removal, including the claimed content of water removal, would have been operable within the scope of patentees invention and with a reasonable expectation of success. Criticality for such, clearly commensurate in scope with the claims, not having been demonstrated on this record. Mere attorneys arguments unsupported by factual evidence, are given little weight. ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument."). See also In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); Ex parte George, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991).

Relative to Venkatraman et al—It is urged and maintained that the instantly claimed invention is obvious within the meaning of 35 USC 103(a) over Venkatraman et al as per reasons clearly stated in the Grounds of Rejection supra. The crux of Counsel's arguments appears to hinge on there being no phase separation since dehydration by at least 50 is not taught by Venkatraman et al. To this end, it is maintained that the content of water removal, although generic, such is a necessary implication that any water content removal, including the claimed content of water removal, would have been operable within the scope of patentees invention and with a reasonable expectation of success. Criticality for such, clearly commensurate in scope with the claims, not having been demonstrated on this record. Mere attorneys arguments unsupported by factual evidence, are given little weight. ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing

appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument."). See also In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); Ex parte George, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991). Moreover, Counsel is arguing criticality for something not even in the claims. Note that the claims call for removing water in minuscule amounts and not by at least 50 wt.% as argued by Counsel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy M. Reddick whose telephone number is (571)272-1110. The examiner can normally be reached on Monday-Friday, 6:30 a.m.-3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571)272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Judy M. Reddick
Primary Examiner
Art Unit 1713

JMR
4.19.04